#### ORIGINAL RESEARCH ARTICLE



# Home management by remote self-monitoring in intermediate- and high-risk pregnancies: A retrospective study of 400 consecutive women

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#### **Abstract**

Introduction: Home management in general is considered to improve patient wellbeing, patient involvement and cost-effectiveness, for obstetric patients as well. But concerns regarding inclusion of intermediate- and high-risk pregnant women are an issue and a limitation for clinical implementation. This retrospective study evaluated the outcome and safety of extended remote self-monitoring of maternal and fetal health in intermediate- and high-risk pregnancies.

Material and methods: The study reports on 400 singleton pregnancies complicated by preterm premature rupture of membranes (PPROM), fetal growth restriction, preeclampsia, gestational diabetes mellitus, high-risk of preeclampsia, or a history of previous fetal or neonatal loss. Remote self-monitoring was performed by pregnant women and included C-reactive protein, non-stress test by cardiotocography, temperature, blood pressure, heart rate, and a questionnaire concerning maternal and fetal wellbeing. Data were transferred to the hospital using a mobile device platform and evaluated by healthcare professionals. In case of non-reassuring registrations, the pregnant women were invited for assessment at the hospital. Primary outcome was perinatal death. Secondary outcomes were other maternal and perinatal complications.

Results: No severe maternal complications were observed. Nine fetal or neonatal deaths occurred, all secondary to malformations, severe fetal growth restriction, extreme prematurity or lung hypoplasia in cases of PPROM before 24 weeks. Even in the latter group, fetal and neonatal survival was 78% (18/23) and rose to 97% (60/62) when PPROM occurred after a gestational age 23+6 weeks. None of the fetal or neonatal deaths were attributable to the home-management setting.

Conclusions: Home-monitoring including remote self-monitoring of fetal and maternal well-being in intermediate- and high-risk pregnancies seems to be a safe alternative to inpatient or frequent outpatient care, which sets the stage for a new way of thinking

Abbreviations: FGR, fetal growth restriction; GA, gestational age; PE, preeclampsia; PPROM, preterm premature rupture of membranes.

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of hospital care. The implementation process included staff training workshops and development of patient enrollment practice with clarification of expectations and responsibilities, which can be crucial to the results.

#### **KEYWORDS**

fetal growth retardation, home care, perinatal mortality, pregnancy, preterm premature rupture of fetal membranes

#### 1 | INTRODUCTION

Home management of patients in general is considered to improve patient well-being, patient involvement and cost-effectiveness, for obstetric patients as well.<sup>1</sup> While case-series of homemonitoring including women with pregnancy complications show that this management may be safe<sup>2-6</sup> and might even improve some fetal and maternal outcomes,<sup>5</sup> severe but rare complications requiring immediate intervention such as prolapse of the umbilical cord or preterm birth raise concern about its use in high-risk pregnancies.<sup>7</sup>

Most previous studies of home-management report that highrisk pregnancies are monitored by daily or weekly visits either by healthcare professionals visiting pregnant women in their homes or by pregnant women attending check-ups at the outpatient clinic, a significant bias in the assessment of possible effects of homemonitoring on safety and outcome. An extensive form of home management has been practiced by Aarhus University Hospital, Denmark, since 2011.

Home management of high-risk pregnant women has therefore developed as an alternative to conventional management encompassing hospitalization or frequent visits in the outpatient clinic. Moreover, it may be an attractive, cost-effective alternative to conventional management in the case of intrauterine growth restriction, preeclampsia (PE)/increased risk of PE, or adverse obstetric history requiring continuous monitoring.<sup>5,8,9</sup> More recently, telemedicine and home-monitoring have demonstrated potential in keeping as many patients as possible out of the hospital during the present COVID-19 pandemic.<sup>10</sup>

However, knowledge on feasibility and safety of home management including self-monitoring in intermediate- and high-risk pregnant women is still needed.

The aim of this study was to address safety and outcome of 400 intermediate- and high-risk pregnancies managed by homemonitoring, and addresses aspects of importance for the safety of home management in the form of remote self-monitoring.

#### 2 | MATERIAL AND METHODS

This retrospective study included singleton pregnant women enrolled in the home monitoring program at Aarhus University Hospital, Denmark, between February 2011 and December 2019.

# Key message

An extended setup of home-monitoring including remote self-monitoring in intermediate- and high-risk pregnancies was feasible, safe and with outcomes comparable to or better than reported with inpatient care. Home-monitoring should be considered as an option in women with selected complications.

## 2.1 | Telemedicine setup

Self-monitored data on maternal and fetal well-being were transferred electronically from the woman to the hospital (remote self-monitoring) with a mobile device including a telemedicine platform as the primary source for communication and data transfer. Home management was offered in case of preterm premature rupture of membranes (PPROM), fetal growth restriction (FGR), mild/moderate PE, high risk of PE and where pregnancy was complicated by other factors including former intrauterine or neonatal death, in which case management was tailored to meet the individual's needs.

## 2.2 | Study population

All included women attended the publically funded (free for all women) offer of a 1st trimester scan for viability, number of fetuses, crown-rump length, and estimated due date using the formula of Robinson et al., <sup>11</sup> and assessment of gross anatomy. Additionally, a 2nd trimester anomaly/growth scan was offered, also free of charge. Only native Danish-speaking or English-speaking women were included, as the setup relies very much on communication by phone.

Women with PPROM were diagnosed by constant leakage of amniotic fluid, inspection confirming amniotic fluid in the posterior vaginal fornix, and oligo or anhydramnios diagnosed by ultrasound before gestational age (GA) 34+0 weeks. Initial management included admission to the obstetric department, bacteriological assessment of urine, group B streptococcus prophylaxis the first 7 days, and antenatal corticosteroids (only at GA ≥23+5 weeks). Eligibility criteria for home monitoring included no signs of chorioamnionitis or preterm labor for at least 72 hours and GA 20+0 weeks. However, throughout the study period, exclusion criteria

in women with PPROM became less restrictive regarding observational period at hospital and cervical length. No restrictions were applied as to fetal position and distance from home to hospital.

Women with PE were diagnosed according to the International Society for the Study of Hypertension in Pregnancy (ISSHP) $^{12}$  definition: systolic blood pressure at  $\geq$ 140 mm Hg and/or diastolic blood pressure at  $\geq$ 90 mm Hg on at least two occasions measured 4 hours apart in previously normotensive women, accompanied by one or more of the following new-onset conditions at or after 20 weeks of gestation:

- Proteinuria (i.e. ≥30 mg/mol protein: creatinine ratio; ≥300 mg/24 h; or ≥2 + dipstick), or
- 2. Evidence of other maternal organ dysfunction or
- 3. Uteroplacental dysfunction (such as FGR or abnormal umbilical artery Doppler waveform analysis).

PE severity was assessed by symptoms and blood samples. Women with FGR were diagnosed by a specialist in fetal medicine if the estimated fetal weight was below the 10th centile and assessment by AFI and Doppler parameters (arteria umbilicalis flow, arteria uterina flow and middle cerebral artery) on indication of placental insufficiency. Most of these women were not admitted to the obstetric department initially but attended the home monitoring program immediately after being diagnosed. Antenatal glucocorticoids were recommended on an individual basis according to national recommendations. <sup>13</sup>

No exclusion criteria were applied to the lower limit of GA or fetal malformations, but only singleton pregnancies were included, since the cardiotocography device could be used only in singleton pregnancies.

All women meeting the inclusion criteria for home-monitoring were informed by a senior doctor (physician) and gave their consent to participate in the home-monitoring setup.

However, women included as alternative to inpatient care were included only after monitoring as a precaution to rule out women with rapid developing complications.

# 2.3 | Patient involvement in the home-monitoring

For each woman enrolled in home-monitoring, a detailed monitoring plan was written in the electronic healthcare report. Standard monitoring plans were available for PPROM and PE. In the case of PPROM, the daily self-assessment consisted of C-reactive protein, non-stress test by cardiotocography, temperature, blood pressure, heart rat and a questionnaire concerning abdominal pain, contractions, fetal movements and maternal wellbeing in general. All examinations were self-administered by the pregnant woman at home. Every second week, she was offered an assessment in the outpatient clinic including an ultrasound scan of estimated fetal weight and amniotic fluid volume, test for leukocytes in the urine, and a blood sample including white blood cell count.

In the case of other indications for home management (FGR, PE, high risk of PE and other), the frequency and contents of the

self-assessment were tailored to meet the individual woman's clinical condition and included measurement of blood pressure, test for proteinuria, cardiotocography, and a questionnaire concerning fetal movements, symptoms of PE and maternal wellbeing in general.

Daily evaluation by healthcare professionals was based on information transferred digitally to the hospital by the OpenTele system. All assessments of results were pre-booked in the electronic healthcare report at a date and time agreed with the woman. Furthermore, all included women could contact the department day and night by any concern. As a general rule and unlike women with normal pregnancies, women on home-monitoring were invited for assessment at the outpatient clinic or acute obstetric ward on even low levels of suspicion of anomaly.

# 2.4 | Patient and public involvement

The pregnant women and their partners were involved in the development of the Open Source platform developed during the project (using participatory design) as well as participating in the implementation process (participated in implementation- and staff training workshops), but they were not involved in the defining of research questions, outcome measures or evaluation of results.

#### 2.5 | Outcomes

The following information was obtained from medical records. Maternal and pregnancy outcomes included pre-pregnancy maternal age (years), body mass index (kg/m²), parity, cervical length at inclusion, GA at PPROM, PE, chorioamnionitis, episodes of vaginal bleeding, prolapse of umbilical cord, abruptio placentae, GA at delivery, mode of delivery, and indication for planned and emergency cesarean section.

Chorioamnionitis was diagnosed by an obstetrician on the basis of clinical symptoms (maternal fever >37.9°C, uterine contractions or fetal tachycardia >160 bpm) and biochemical symptoms (elevated C-reactive protein and white blood cell count) of infection.

Fetal and neonatal outcomes included presence or absence of structural anomalies, gender of the newborn, Apgar score below five at 1 minute, birthweight/birthweight Z-score and status (live-born, neonatal death and intrauterine death).

Home-monitoring outcomes were gestational age at inclusion, days included in home-monitoring, number of monitoring sessions and rehospitalization.

Obstetric and perinatal outcomes: Two subgroup analyses of PPROM (occurring before GA 24+0 weeks; occurring at or after GA 24+0 weeks) were performed, as complication rate is strongly associated to GA at PPROM and active treatment is offered from GA 24+0 weeks.

Perinatal outcomes: Rates of intrauterine and neonatal death were also presented in subgroups (delivery before GA 28+0 weeks; delivery



at or after GA 28+0 weeks) and GA 28+0 weeks was chosen, as this GA represent an important marker in regard to perinatal survival.

## 2.6 | Statistical analyses

Means or medians if a normal distribution was rejected by quantile-quantile plots [QQ-plots], which were performed for each outcome. Also, 95% confidence intervals (CI) or ranges were shown. In dichotomous outcomes, numbers and percentages were given. The few missing observations were excluded from analyses. Statistics were performed in STATA 14 (Stata Corp., College Station, TX, USA).

## 2.7 | Ethical approval

As a quality control cohort study, according to Danish Legislation, this study did not require an ethical approval.

#### 3 | RESULTS

In total, 400 women were included in remote home management during the study period. Characteristics at inclusion are shown in Table 1. The results are described below for each indication.

Very few (<10) women were either excluded from or opted-out of the home-monitoring management because of non compliance, or because of technical issues with the equipment.

# 3.1 | PPROM

This group comprised 85 women (Table 2), of whom 23 presented with PPROM before GA 24+0 weeks and 67 before GA 28+0 weeks. The median GA at PPROM was 26.1 weeks (range 15.4–33.3), median interval from PPROM to delivery was 18 days (range 3–158 days) and median GA at delivery was 31.6 weeks (range 24.3–38.0). Cervical length at inclusion varied from 6 to 57 mm (mean 31 mm). When restricting the group to PPROM <24 weeks, the mean interval from PPROM to delivery was 48 days (range 7–158), and GA at delivery was 29.3 weeks (range 24.3–38.0). In total, 15% developed signs of chorioamnionitis. No severe cases were observed as all cases were identified in the initial stage and immediately admitted to the obstetric department.

The chance of fetal and neonatal survival in pregnancies complicated by PPROM before GA 24+0 weeks was 78% (18/23), whereas survival rose to 97% (60/62) after GA 23+6 weeks (Table 3). One baby died neonatally after delivery at GA 33+5 weeks. By 20 weeks, severe chylothorax was diagnosed; although pleura-amnio shunts were applied multiple times at intrauterine procedures, the baby had lethal pulmonary hypoplasia.

Finally, no cases of intrauterine death, delivery, prolapse of umbilical cord or severe chorioamnionitis occurred at home.

TABLE 1 Characteristics of included women

		PPROM	PPROM (n = 85)	PE and	PE and FGR ( $n = 94$ )	High risk	High risk of PE $(n=151)$	DM and	DM and GDM ( $n = 23$ )	Other (N = 47)	V = 47)
Demographics Maternal age (years)	Mean (95% CI)	n (85)	30.7 (29.7-31.7)	n (94)	31.0 (29.9-32.1)	n (151)	32.0 (31.2-32.9)	n (23)	30.6 (28.6-32.6)	n (47)	32.6 (31.4-33.8)
Pre-pregnancy BMI ( $kg/m^2$ )	Mean (95% CI)	n (77)	24.7 (23.3-26.1)	n (92)	27.5 (26.2–28.9)	n (149)	26.3 (25.3-27.3)	n (23)	27.9 (25.6-30.3)	n (44)	24.1 (22.6-25.5)
Nulliparity	n (%)	n (76)	39 (51.3)	n (93)	65 (70.0)	n (147)	59 (39.1)	n (23)	8 (34.8)	n (43)	7 (16.3)
Characteristics at inclusion											
Gestational age at inclusion (weeks)	Median (range)	n (85)	See Table 2	n (94)	n (94) 33.8 (13.6–37.86)	n (151)	n (151) 31.4 (12.0–38.7)	n (23)	n (23) 33.9 (26.3-35.9) n (47) 32.1 (20.0-38.9)	n (47)	32.1 (20.0–38.9)
Cervical length	Mean (95% CI) (range)	n (68)	n (68) 30.5 (27.5-33.6) (5.7-57.0)	I	I		I		I		I
Fetal presentation at inclusion			Any		Any		Any		Any		Any

Abbreviations: BMI, body mass index; DM, pregestational diabetes melitus; FGR, fetal growth restriction; GDM, gestational diabetes melitus; PE, preeclampsia; PPROM, preterm premature rupture of

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			PPROM (n	1 (n = 85)	PE and I	PE and FGR ( <i>n</i> = 94)	High risk	High risk of PE $(n = 151)$	DM and GDM ( $n = 23$ )		Other (n = 47)	= 47)
GA PPROM (weeks)	Median(range)		n (85)	26.1 (15.4-33.3)		ı		ı	ı		ľ	
	Median (range)	PPROM <24+0		22.7 (15.4-23.9)		1		I	I		·	
	Median (range)	PPROM ≥24+0		30.1 (24.0-33.3)		I		ı	I		·	ı
GA delivery (weeks)	Median (range)		n (85)	31.6 (24.3–38.0)	n (94)	36.3 (28.0-40.0)	n (151)	38.1 (27.3-40.9)	n (23) 38.6	38.6 (33.6-40.4)	n (47)	37.4 (30.7-40.4)
	Median (range)	PPROM <24+0		29.3 (24.3-38.0)		I		I	I		·	
	Median (range)	PPROM ≥24+0		33.7 (29.9-38.0)		ı		1	ı		·	
Days to delivery <sup>a</sup>	Median (range)		n (85)	18 (3-158)	n (94)	12.5 (0-183)	n (151)	30 (4-193)	n (23) 30 (;	30 (10–71)	n (47)	24 (1-124)
	Median (range)	PPROM <24+0		48 (7-158)		ı		1	1		·	
	Median (range)	PPROM ≥24+0		14 (3-69)		I		I	I		·	
Number of monitorings	Median (range)		n (85)	10 (2-96)	n (93)	7 (1-44)	n (150)	13 (1-72)	n (23) 6 (3-9)		n (47)	11 (2-35)
Risk of readmission	n (%)		n (85)	23 (27.1)	n (94)	14 (14.9)	n (151)	29 (19.2)	n (23) 1 (4.3)		n (47)	6 (12.8)
Preeclampsia	n (%)		n (85)	1		ı	n (151)	32 (21.2)	I			
Chorioamnionitis	n (%)		n (85)	13 (15.3)		I		ı	I		,	
	n (%)	PPROM <24+0		3 (13.0)		ı		I	I		·	
	n (%)	PPROM ≥24+0		10 (16.1)		I		1	I		·	
	Median (range)	GA at PPROM		25.7 (19.6-32.0)		ı		1	I		·	
Abruptio placentae	n (%)		n (85)	4 (4.7)	n (94)	0 (0)	n (151)	0) 0	n (23) 0 (0)		n (47) (	0 (0)
	n (%)	PPROM <24+0		2 (8.7)		ı		ı	I			
	n (%)	PPROM ≥24+0		2 (3.2)		1		1	I			
	Median (range)	GA at PPROM		24.4 (16.6-26.1)		ı		1	ı		•	
Vaginal bleeding	n (%)		n (85)	7 (8.2)		ı		ı	ı		·	1
	n (%)	PPROM <24+0		4 (17.4)		ı		1	ı		•	
	n (%)	PPROM ≥24+0		3 (3.8)		I		1	I		·	ı
	Median (range)	GA at PPROM		22.3 (19.9-26.3)		ı		1	ı		·	
Prolapse of umbilical cord (before delivery)	n (%)		n (85)	(0) 0								
Delivery: <i>mode</i> and indication			n (80)		n (91)		n (149)		n (23)		n (46)	Scandir
Vaginal	n (%)			38 (47.5)		33 (36.3)		72 (48.3)	11 (3	11 (34.4)	•	20 (42.6)
Emergency SC	n (%)			35 (43.8)		32 (35.2)		44 (29.5)	9 (39.1)	9.1)	•	10 (21.3)
FGR	n (%)			I		6 (18.8)		4 (9.3)	I			
Fetal, other	n (%)			13 (39.4)		8 (25.0)		8 (18.6)	2 (25.0)	5.0)	-,	5 (50)

(Continued)

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TABLE

16 (34.0) 10 (62.5) 2(12.5)3 (18.7) 1 (10) 4 (40) Other (n = 47)DM and GDM (n = 23)2 (25.0) 1 (33.3) 1(12.5)3 (37.5) 1(33.3)1(33.3)3 (13.0) High risk of PE (n = 151)14 (43.8) 11 (25.6) 33 (22.1) 12 (27.9) 8 (18.6) 7 (21.9) 4(12.5)3 (9.4) 3 (9.4) 1 (3.1) PE and FGR (n = 94)12 (48.0) 26 (28.6) 5 (20.0) 5 (20.0) 9 (28.1) 7 (21.9) 2 (6.3) 2 (8.0) 1 (4.0) 11 (33.3) 2 (28.6) 2 (28.6) PPROM (n = 85)9 (27.3) 7 (8.8) 3 (42.9) n (%) n (%) n (%) n (%) n (%) (%) u n (%) n (%) (%) u (%) u Maternal request Maternal, other Maternal, other Preeclampsia Preeclampsia Fetal, other Elective SC Dystocia Breech Breech FGR

preterm premature rupture pregestational diabetes melitus; FGR, fetal growth restriction; GA, gestational age; GDM, gestational diabetes melitus; PE, preeclampsia; PPROM, Abbreviations: DM, membranes.

GA at PPROM <24+0: (n = 23).

GA at PPROM  $\geq 24+0$ : (n=62). <sup>a</sup>From PPROM or inclusion in the other groups.

# 3.2 | PE and FGR

This group included 94 singleton pregnant women with either PE or FGR or both. The median GA at inclusion was 33.8 weeks (range 13.6–37.9; Table 1) and the median GA at delivery was 36.0 weeks (range 28.0–40.0; Table 2). Two fetuses died; one with major malformations and hydrops fetalis at GA 34+5 weeks, the other with severe FGR from week 20 and a birthweight of 635 g at GA 28+5 weeks. In the latter case, home management was arranged in agreement with "parental wishes" and on indication of increased risk of PE. We observed no intrauterine deaths or cases of eclampsia at home (Table 3). Still, the mean birthweight corrected for GA supports a diagnosis of FGR (mean Z-score −1.5, corresponding to the 6.7 percentile [< −15% of the expected birthweight]).

# 3.3 | High risk of PE, pregestational diabetes melitus/gestational diabetes mellitus, and other

In total, 221 pregnant women were included by indication of high risk of PE and pregestational diabetes melitus/gestational diabetes mellitus, and on other indications (Table 2). Other indications included women who had previously experienced intrauterine death or neonatal loss, pregnancies where fetal malformation was diagnosed, or women with recurrent contacts and concerns because of reduced fetal movements. No major complications were seen in this group, including no intrauterine deaths or neonatal deaths (Table 3). In all three subgroups, median GA at delivery was >37 weeks, and no severe complications were observed. In the subgroup of women with high risk of PE, 21% developed PE.

#### 3.4 | Home-monitoring

The longest duration of inclusion was 194 days; however, the median varied from 12.5 to 30 days and was shortest in the PE group (Table 2). Around 6–13 monitoring sessions were performed on average in each woman; again, the lowest number was seen in the group of women with PE. In all, 73 (18.3%) women experienced readmission during their inclusion in home-monitoring; the median re-admission was 1 (minimum 1, maximum 7 times). The risk of readmission was highest in the PPROM and high risk of PE group (27% and 19%, respectively).

# 4 | DISCUSSION

To our knowledge, this is the hitherto largest study reporting outcome of intermediate and high-risk obstetric patients managed by homemonitoring of maternal and fetal wellbeing. Our results provide evidence of the benefits of home management in a range of intermediate and high-risk pregnancy complication. Even in a setup with extended patient involvement by remote self-monitoring, severe outcomes such

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			PPROM $(n = 85)$	(n = 85)	PE and	PE and FGR ( <i>n</i> = 94)	High risk	High risk of PE $(n = 151)$	DM and	DM and GDM ( $n = 23$ )	Other $(n = 47)$
Gender (male)	n (%)		n (84)	49 (58.3)	n (92)	52 (56.5)	n (151)	85 (56.3)	n (23)	9 (39.1)	n (46) 20 (43.5)
Birthweight (g)	Mean (95% CI)		n (83)	1757 (1611–1902)	n (94)	2282 (2116-2449) n (150)	n (150)	2920 (2794-3047) n (21)	n (21)	3670 (3356-3983)	n (47) 2953 (2754-3152)
Birthweight corrected for Mean GA (Z-score, Hadlock) (95	Mean (95% CI)		n (83)	-0.6 (-0.8 to -0.3)	n (94)	-0.6 (-0.8 to -0.3) n (94) -1.5 (-1.8 to -1.1) n (150)	n (150)	-0.5 (-0.7 to -0.3) n (21) 1.0 (0.3-1.6)	n (21)		n (47) -0.2 (-0.5 to 0.2)
Apgar <7 at 5 min (in liveborn)	n (%)		n (77)	8 (10.7)	n (90)	2 (2.3)	n (145)	0 (0)	n (21)	(0) 0	n (47) 0 (0)
Apgar <4 at 5 min (in live n (%) born)	(%) u		n (77)	4 (5.3)	n (90)	(0) 0		1		I	1
Intrauterine death	n (%)	All	n (85)	2 (2.4)	n (94)	2 (2.1)	n (151)	0 (0)	n (23)	0 (0)	n (47) 0 (0)
	(%) u	GA at delivery <28+0		2 (11.1)	ı	I		I		I	1
	n (%)	GA at delivery ≥28+0		(0) 0	1	I		I			J
	(%) u	GA at PPROM <24+0		1 (4.3)	I	I		1		I	I
	n (%)	GA at PPROM ≥24+0		1 (1.6)	1	1		I		ı	ı
Neonatal death (28 days)	n (%)	All	n (85)	5 (5.9)	n (94)	(0) 0	n (151)	0 (0)	n (23)	0 (0)	n (47) 0 (0)
	n (%)	GA at delivery <28+0		4 (21.1)	ı	I		I			ı
	(%) u	GA at delivery ≥28+0		1 (1.5)	I	1		I		I	1
	(%) u	GA at PPROM <24+0		4 (17.4)	ı	I		I		ı	J
	n (%)	GA at PPROM ≥24+0		1 (1.6)	ı	I		1		I	1

Abbreviations: DM, pregestational diabetes melitus; FGR, fetal growth restriction; GA, gestational age; GDM, gestational diabetes melitus; PE, preeclampsia; PPROM, preterm premature rupture of membranes.

GA at PPROM <24+0 (n = 23). GA at PPROM  $\geq 24+0$  (n=62).

GA at delivery <28+0 (n = 18).

GA at delivery  $\geq 28+0$  (n = 67).



as fetal or neonatal death were rare. No severe fetal or maternal complications occurred at home, and none of the few fetal and neonatal deaths was attributable to the home management setting.

We included 400 women over a relatively short time span. Indications for inclusion ranged from maternal indication based on history of previous fetal or neonatal loss to maternal high-risk pregnancies such as PE and fetal high-risk indications such as severe FGR, PPROM and cervical insufficiency. As a retrospective cohort study, bias associated to this study design could affect our results. However, the size of the study population and clinical management by guidelines is a major strength.

Management by home-monitoring was implemented as an option to standard care, and only native Danish- or English-speaking women were included. We did not have access to socioeconomic or demographic information on included women, both of which could represent possible sources of selection bias.

#### 4.1 | PPROM

#### 4.1.1 | PPROM < 24 weeks

In this very high-risk group, perinatal survival was high (18/23 [78%]) compared with published "in hospital" series (Dinsmoor [survival rate 47%])<sup>14</sup> and Linehan [23% live born],<sup>15</sup> but was comparable to results reported by Soylu (survival rate 76%).<sup>16</sup> However, we included women only if they reached 20 weeks of gestation, whereas Dinsmoor et al.<sup>14</sup> included all women with PPROM between 16.9 and 24.0 weeks and Linehan<sup>15</sup> included only those whose delivery took place later than 24 hours after PPROM occurring between 14 and 23 weeks. Ellested et al.<sup>17</sup> showed that only 11% of women with PPROM (20–34 weeks) delivered <72 hours after PPROM. This supports the likelihood that our survival rate would still be high, even if women delivering before 48 hours were included.<sup>17</sup> Another study reporting on "in hospital" management of PPROM from 20 to 34 weeks of gestation found a survival rate of 50%, <sup>18</sup> which is below the rate reported by us.

In a home management setting, Petit et al. <sup>19</sup> reported a survival rate comparable to ours; however, they only included pregnancies reaching 24 weeks, compared with 20 weeks in our study. Only two randomized controlled studies (116 women) comparing home vs hospital management were included in a Cochrane review from 2014. <sup>2</sup> No significant difference in survival rate was found; however, the study was underpowered (relative risk [RR]:1.93 [0.19, 20.05]).

Finally, our findings of latency from PPROM to delivery (48 days) and median GA at delivery (29.3 weeks) were positive compared with former studies by Dinsmoore et al. (13 days; 25.8 weeks) and Soylu et al. (45 days).

# 4.1.2 | PPROM ≥24 weeks

The survival rate was also very high (60/62 [97%]), especially considering that cases with congenital malformations were not excluded.

Deaths were attributable to fetal malformations or severe intrauterine growth restriction, both occurring after re-hospitalization. GA at delivery (33.7 weeks) was comparable with other studies, <sup>4,5</sup> which also have lower latency in "in hospital" management compared with home management.

In PPROM, the risk of chorioamnionitis is of major concern. We found this risk to be comparable to that reported in other series.<sup>3,5</sup>

# 4.2 | PE, FGR, risk of PE, pregestational diabetes melitus, gestational diabetes mellitus and other indications

To the authors' knowledge, no previous studies have investigated home management in women with these indications. However, remote self-monitoring appears safe. No severe complications due to home-monitoring were observed.

#### 4.3 | Patient experience

A qualitative study, on a sample of the population included in this study, showed that the pregnant women experienced less anxiety and more freedom and flexibility in the home-monitoring setting than they thought they would have experienced under a conventional regime. Women with PPROM in particular explained that avoiding a very long admission was of huge value to them. They also found that it was important to be involved in their treatment. Finally, they actually felt that they had better opportunities for contacting healthcare professionals in the home setting than during admission.

In the subgroup of very high-risk women, where fetal or neonatal death was a risk, home-monitoring was still preferred by many. These women explained that being at home in this situation was less stressful. They found it meaningful and valuable to be together with their family and close relatives during the process of handling grief and sorrow instead of being isolated during hospitalization. These findings are in agreement with previous studies. <sup>2,8,21</sup>

In this study, only very few patients (<10) were excluded after inclusion or opted-out during home-monitoring, which underlines the feasibility and acceptance of home-monitoring.

#### 4.4 | Safety

We developed the home-monitoring project at our department over several years, and a broader implementation of home-monitoring requires a change in current practices which will always represent a challenge. Secondly, implementation of home-monitoring as a standard of care was preceded by training workshops with midwives, nurses and doctors, at which results and experience were presented and discussed. Former patients also participated in these workshops.

Some of the most important lessons learned were that enrollment should include a thorough and open discussion of expectations and shared responsibility with the couple; it should be mentioned that adverse outcomes could also happen in the home setting and that the women were responsible for contacting the department in case of changed symptoms or if they had any concerns. Not least, the staff was aware that calls from women on home-monitoring should be managed as a call from a high-risk women and not as a call from a woman with a normal pregnancy, wherefore the threshold for assessment at the hospital should be very low.

Despite their pregnancy complications, only 18% of the women in this study were re-admitted, a result that supports extended homemonitoring as a safe and sufficient patient management option.

Regarding generalizability, safety and results of remote selfmonitoring of high-risk obstetric patients is inevitably dependent of more factors than in-patient management. In our experience, development of and compliance with management guidelines and training of staff, including how to respond to calls from patients in home-monitoring, were important factors in maintaining quality of care and safety. We therefore consider our results generalizable to comparable clinical settings.

#### 4.5 | Cost-effectiveness

The cost-effectiveness of a large-scale implementation of homemonitoring of women with pregnancy complications was assessed in a report by the Danish Ministry of Health, including data from Aarhus University Hospital. National implementation was found to be cost-effective, with a net saving of DKK 18 million over a 5-year period. <sup>22</sup> The 85 women with PPROM "saved" >1500 days of hospitalization, and the 315 women in the other groups saved >4200 days of hospitalization or outpatient visits. These reduced costs are in accordance with formerly reported savings of 40%–50% compared with in-patient hospital management. <sup>7,21</sup>

# 5 | CONCLUSION

Home management of intermediate- and high-risk pregnant women including remote self-monitoring is feasible and appears beneficial in terms of maternal and fetal safety. Implementation should include education of staff and explicit communication about expectations and responsibility with enrolled women.

#### CONFLICT OF INTEREST

None.

#### **AUTHOR CONTRIBUTIONS**

OBP implemented the home-monitoring model, designed the study, provided quality control on statistical analysis, and reviewed and edited the main manuscript text. ARZ and OBP did all statistical analysis, produced all tables and figures, and wrote the main manuscript

text and supplementary materials. LHv, LHo, JDS and MK initiated the project, reviewed and edited the main manuscript text and supplementary materials. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. OBP is the guarantor.

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